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**Amendment to the Drawings:**

The attached sheets of drawings include the amendments to Figs. 4 and 5. The attached figures substitute the original figures 4-5.

The figures have been amended to remove the shading of some of the boxes.

Attachment: Replacement Sheets (2)

**REMARKS/ARGUMENTS**

Claims 1-7, 13-22, 28-45 remain pending in the application. Claims 8-12, 23-27, and 38-42 have been cancelled. Claims 1-6, 15-21, and 31-36 have been amended. The canceled claims have been cancelled due to an election from a Restriction Requirement issued by the Examiner. Therefore, the claims are not cancelled for any reason related to patentability and are cancelled without prejudice or disclaimer. Support for these amendments can be found through the specification (i.e. page 19, lines 8-13) and original claims. Applicants assert that no new matter is presented by these amendments and respectfully request entry of the same.

***Drawings Objections***

Drawings are objected to because of the dark shading of some boxes. Applicant has amended the drawings and hereby submits replacement sheets of Figures 4 and 5. The dark shading of the boxes has been removed. Applicant hereby state that no new matter has been entered with this amendment.

***Objection to the Specification***

The abstract has been objected to because the second sentence is incomplete. Applicants have amended the abstract to complete the second sentence, support for this amendment can be found i.e. page 3, line.

The specification has been objected to because it contains an embedded hyperlink. The specification has also been objected to because of informalities because the word

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"invention" is misspelled. Applicants have amended the specification to correct these informalities.

No new matter has been entered by these amendments.

***Objection to the Claims***

Claims 4, 15, 19, 30, and 45 are objected to because of informalities. Claims 4, 15 and 19 have been amended to correct such informalities. No new matter has been entered by these amendments.

***Claim Rejections under 35 U.S.C. § 101***

Claims 1-7 and 13-15 are rejected as allegedly claiming an invention directed to non-statutory matter.

Applicant respectfully disagrees. Claims 1 - 10 encompass a method performed on a computer. Gene cluster analysis does provide results of data manipulation that are "useful, concrete and tangible" such as for associating biological significance with experimental results of a microarray, see paragraph on page 1, lines 16.

Furthermore, According to *State Street Bank and Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed.Cir.1998), the lack of physical result should not matter. "In *Diehr*, the Court explained that certain types of mathematical subject matter, standing alone, represent nothing more than abstract ideas until reduced to some type of practical application, i.e., 'a useful, concrete and tangible result.'" *Id.* at 13.

The patented invention in *State Street Bank and Trust Co.* was "a data processing system . . . for implementing an investment structure . . . as an administrator and

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accounting agent for mutual funds.” *Id.* at 3. This invention produced no physical result, but the court upheld the patent because the invention produced “a useful, concrete and tangible result” *Id.* at 14 quoting *In re Alappat*, 33 F.3d 1526, 1540-41, 31 U.S.P.Q.2D (BNA) 1545, 1554 (Fed. Cir. 1994).

*State Street Bank and Trust Co.* is controlling authority that precludes rejecting the instant application because the invention lacks “any physical result performed outside of a computer.” Although the Computer-Implemented Analysis of Gene Clusters produces no physical result outside of a computer, gene cluster analysis does provide results of data manipulation that are “useful, concrete and tangible” for drug discovery.

Claims 1-7, 13-22, 28-37 and 43-45 are rejected as allegedly not being supported by either an asserted utility or a well established utility. The examiner also alleges that the instant claim fails to recite any correlation step and the specification does not disclose any such step or “use” for the claimed method.

The well established utility is supported by specific, substantial and credible references using the claimed method such as for research in molecular biology to analyze massive amounts of data from experiments for example in studies of diseases such as colon cancer, brain tumors, etc. The one skilled in the art will understand that the use of a method of gene expression analysis is a critical tool in understanding biological processes.

Furthermore, in the cited reference by the Examiner, ZENG et al (US 6,263,287), claim 1 does not recite the correlation step or use for the claimed method. However, the claim has been held granted.

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Next, the Examiner alleges that on page 19, the specification discloses that in some embodiments the "analyzing" step includes selecting data for further analysis; i.e. the invention steps are reiterated and therefore the analyzing performs further research on the invention itself. Applicant respectfully disagrees. The specification on page 20, lines 17-18, indicate that the expression levels obtained are analyzed *according to* the selected at least one biological characteristic. Therefore, the invention step does not perform further research on the invention itself.

In summary, this rejection under section 101 should be withdrawn.

***Claim Rejections under 35 U.S.C. § 102***

Claims 1-4, 6, 13-19, 21, 28-34, 36, and 43-45 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by ZHENG et al (US 6,263,287).

The Examiner indicates that ZHENG teaches a method, system, and program for manipulation and analysis of gene expression data wherein gene expression data is received/provided, and the data is clustered with regard to at least one biological characteristic therefore anticipating claims 1-2, 4, 6, 16-17, 19, 21, 31-32, 34, and 36. The Examiner also indicates that Zheng teaches the use of SQL, thereby anticipating claims 15, 30 and 45. The Examiner further indicates that the Zheng reference teaches the use of data from GenBank and other databases, and further teaches the analysis of clustered data, thus anticipating claims 3, 13-14, 18, 28-29, 33, and 43-44.

Applicant respectfully disagrees. However, for the purpose of expediting the prosecution of the instant application, applicant has amended independent claims 1, 16,

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and 31 to add that the biological characteristics are described using a gene ontology system. Support for this amendment can be found in for example page 19, line 8-13.

As amended, claims 1, 16, and 31, teach a method, system and program for analyzing gene expression obtaining expression levels of a plurality of genes; selecting at least one biological characteristic from a plurality of biological characteristics stored in a database; wherein the biological characteristics comprise genomic information about the genes, structural information about the products of the genes; and biological function of the genes, wherein the biological characteristics are described using a gene ontology system; and further analyzing the expression levels according to the selected at least one biological characteristic.

Zheng et al fails to teach all the limitations of independent claims 1, 16, and 31. More specifically, Zheng fails to teach that the biological characteristics are described using a gene ontology system. Therefore, Applicant respectfully requests withdrawal of the rejection.

Claims 1-4, 6-7, 13-19, 21-22, 28-34, 36-37 and 43-45 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by or, in the alternative, under 103(a) as obvious over Garner et al (US 2003/0033290) and Ogata et al (Nucleic Acids Res. 1999) Vol. 27, No. 1, pp. 29-34).

The Examiner indicates that Garner teaches a method, program and system for analysis of genetic databases wherein gene expression data is obtained and clustered

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according to selected biological characteristics, including genomic information and biological function, thereby anticipating claims 1-2, 4, 6, 16-17, 19, 21, 31-32, 34, and 36. The Examiner states that GANER teaches that the information derived from the clustering analysis may be used to select or recommend genes for further analysis, thereby anticipating claims 3, 18, and 33. The examiner further states that GARNER teaches a variety of database, including KEFF, and use of SQL software, thereby anticipating claims 13-15, 28-30, and 43-45.

The Examiner also indicates that OGATA provides support that KEGG comprises information with regard to orthologous genes, therefore GARNER's teaching of KEGG is inherently a teaching for biological information comprising orthologous genes, and thus claims 7, 22, and 37 are anticipated and/or made obvious.

Applicant respectfully disagrees. As amended, GARNER fails to teach all the limitations of the independent claims 1, 16, and 31. More specifically, GARNER fails to teach that the biological characteristics are described using a gene ontology system. Therefore, Applicant respectfully requests withdrawal of the rejection.

***Claim Rejections under 35 U.S.C. § 103(a)***

Claims 1-6, 13-21, 28-36, and 43-45 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Zheng et al (US 6,263,287) in view of Rocke et al (US 2002/0111742). ).

The examiner asserts that one of the skill in the art would have been motivated to successfully combine ROCKE's dimension reduction with ZHEN's clustering because both teach analyzing large amounts of gene expression data in order to correlate

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differential gene expression with tissue specificity. Applicant respectfully disagrees.

However, as amended, the instant application teach a method, system and program for analyzing gene expression obtaining expression levels of a plurality of genes; selecting at least one biological characteristic from a plurality of biological characteristics stored in a database; wherein the biological characteristics comprise genomic information about the genes, structural information about the products of the genes; and biological function of the genes, wherein the biological characteristics are described using a gene ontology system; and further analyzing the expression levels according to the selected at least one biological characteristic.

The Examiner did not address the additional limitation of independent claims 1, 12, and 31 in the office action. Applicant asserts that none of the cited references teaches that the biological characteristics are described using a gene ontology system. Since the cited references, alone or in combination, do not teach or suggest the presently claimed invention, Applicant respectfully submit that the rejection of claims 1-7, 13-22, 28-37 and 43-45 under 35 U.S.C. 103(a) should be withdrawn.



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**CONCLUSION**

For these reasons, Applicants believe all pending claims are now in condition for allowance. If the Examiner has any questions pertaining to this application or feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at (408) 731-5000.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 01-0431.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By Leticia R. Block  
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Attachments (Replacement Figures 4 and 5)

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